IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
CAMDEN DIVISION

IN RE: VALSARTAN PRODUCTS LIABILITY LITIGATION *This Document Relates to All Actions*	Case No.: 1:19-md-02875-RBK-JS Honorable Robert B. Kugler

OBJECTIONS BY DEFENDANTS AUROBINDO PHARMA USA, INC. AND AUROLIFE PHARMA LLC TO PLAINTIFFS' NOTICE OF VIDEOTAPED DEPOSITION PURSUANT TO FED. R. CIV. P. 30(b)(6)

Defendants Aurobindo Pharma USA, Inc. and Aurolife Pharma LLC (hereinafter "APUSA" and "Aurolife," respectively) hereby submit the below Reservation of Rights and Objections to the Plaintiffs' Notice of Videotaped Deposition Pursuant to Fed. R. Civ. P. 30(b)(6) as follows:

PRELIMINARY STATEMENT

Pursuant to Case Management Order No. 12, the Court "reluctantly" granted plaintiffs leave to "take the Fed. R. Civ. P. 30(b)(6) depositions of Hetero and Aurobindo regarding whether they have 'possession, custody, or control' of the documents/ESI listed in paragraph 6 ('core discovery') of the Court's April 29, 2019 Order [Doc. No. 88]."

On June 27 and July 19, 2019, APUSA and Aurolife produced "core discovery" pursuant to paragraphs 6.b and 6.c of the Court's April 29, 2019 Order, which were directed to "Finished Product/Dose Manufacturer Defendants" and "U.S. Agents for FDA Communications Defendants," respectively. Paragraph 6.a was directed to "API Manufacturer and Supplier Defendants." Except for the FDA communications in their possession, custody or control, neither APUSA nor Aurolife produced the "core discovery" listed in paragraph 6.a.

All disputes regarding the core discovery productions were to be addressed at the court conference on August 14, 2019, pursuant to Case Management Orders 10 and 11 (Docs. 141 and 167, respectively). During the conference, counsel for the Plaintiffs stated "we were able to resolve the Aurobindo issue…other than the more general issue of whether or not they have to produce the Indian company documents."[1] Succinctly, the Court stated: "[T]he legal issue would be do the American companies have 'control' over the foreign companies' documents such that they can request them and the Court can order them to be produced." *See* Tr. of August 14 Conference with Magistrate Judge Schneider (Doc. 200) at 19:19-22.

RESERVATION OF RIGHTS

In providing these objections and responding to the Plaintiffs' Notice and Exhibit A thereto, neither APUSA nor Aurolife waives the right to challenge the relevance, materiality or admissibility of any testimony, information or documents provided, or object to the use of any testimony, information or documents in any subsequent proceeding or trial in any action within this MDL.

APUSA and Aurolife are engaged in the continuing investigation of the matters sought within the Court's April 29, 2019 Order. (Doc. No. 88). APUSA and Aurolife reserve the right to amend, further supplement, or change any response to the Plaintiffs' Notice and Exhibit A thereto as investigation and discovery continue.

GENERAL OBJECTIONS

1. APUSA and Aurolife object to those parts of Plaintiffs' Notice and Exhibit A thereto that are duplicative of the "core discovery" production previously ordered by the Court

[1] When the Court asked if there were any individual issues regarding "Aurobindo," counsel for the Plaintiffs replied "[n]o individual issues, you Honor."

on April 29, 2019 (Doc. 88). Similarly, APUSA and Aurolife further object to the Plaintiffs' Notice and Exhibit A thereto as overbroad and unduly burdensome in that they not limited to paragraph 6.a of the Court's April 29, 2019 Order (Doc. 88) and seeks information and documents already produced by APUSA and Aurolife pursuant to the Court's April 29, 2019 Order.

2. APUSA and Aurolife further object to the Plaintiffs' Notice and Exhibit A thereto as overbroad, unduly burdensome and beyond the scope of the Federal Rules of Civil Procedure in that they call for documents to be produced "at least 20 days prior to the deposition." *See* Plaintiffs' NOD at p. 1. Pursuant to Federal Rule of Civil Procedure 30(b)(2), a 30(b)(6) notice may be accompanied by a Rule 34 request to produce documents *at the deposition*.

3. APUSA and Aurolife further object to the Plaintiffs' Notice and Exhibit A thereto as overbroad and unduly burdensome in that they state the deposition "will continue from day to day, until completed." Pursuant to Fed. R. Civ. P. 30(d)(1), "a deposition is limited to one (1) day of seven (7) hours."

4. APUSA and Aurolife further object to the Plaintiffs' Notice and Exhibit A thereto on the grounds that the terms "valsartan," "documentation," "demonstrating," "contracts," "agreements," "ownership," "agency," "control," "policies," "procedures," "communications," "access," "information," "employees," "agents," "directors," "officers," "requesting," "providing," "regard to," "manufacture," "production process," "regulatory compliance," "testing," "contamination," "directors," "FDA," "regarding," "manufacturing process," "complete," "conduct," "results," "change," "modification," "possession," "custody," "potential," "actual," "use," "solvents," "impurities," "health risks," "posed," "ANDAs," "regulatory filings," "sales," "pricing," "sold," "request(s)," "refused," "denied," "retention,"

"destruction," "meeting agendas," "minutes," "reflecting," "participation," "reference," "sufficient" and "identify" as used therein are vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, unreasonable and neither relevant to any party's claim or defense nor proportional to the needs of the litigation, in that they purport to seek documents not directly related to the recalls, products and the NDMA and NDEA impurities at issue in the litigation.

5. APUSA and Aurolife further objects to the "relevant time period" as overbroad and unduly burdensome, and not proportional in that it would require production of documents unrelated to the events at issue in this case. For the purposes of these Objections and any response to Plaintiffs' Notice and Exhibit A thereto, APUSA and Aurolife will interpret and use "relevant time period" to mean March 21, 2013 to the present.

6. APUSA and Aurolife further object to the Plaintiffs' Notice and Exhibit A thereto as overbroad and unduly burdensome in that they fail to designate one attorney for the Plaintiffs to ask all questions in order to avoid duplicative questioning. The caption on the Notice states that it relates to "all actions."

7. The Court has entered an Electronically Stored Information ("ESI") Protocol (Doc. No. 127). To the extent Plaintiffs seek information or documents that are inconsistent with or beyond the scope of the ESI Protocol, APUSA and Aurolife object and defer to the ESI Protocol.

8. APUSA and Aurolife object to each request to the extent that it seeks documents protected from disclosure by the attorney-client privilege, attorney work product doctrine, or any other applicable privilege. Should any such disclosure by Defendants occur, it is inadvertent and shall not constitute a waiver of any privilege.

9. APUSA and Aurolife incorporate by reference every general objection set forth above into each specific objection set forth below. A specific objection may repeat a general objection for emphasis or some other reason. The failure to include any general objection in any specific objection does not waive any general objection to that request.

OBJECTIONS TO THE "TOPICS" AND "DOCUMENTS REQUESTED ON EXHIBIT A TO PLAINTIFFS' NOTICE

REQUEST No. 1: ***Documentation demonstrating the corporate relationship and organization, including but not limited to ownership, control, parent/subsidiary relationship, and agency relationship, as between and among Aurobindo Pharma USA, Inc., Aurolife Pharma LLC, and Aurobindo Pharma Limited.***

RESPONSE: APUSA and Aurolife object to those parts of this request that are duplicative of the Core Discovery production previously ordered by the Court (Doc. 88). APUSA and Aurolife further object to this Request as overbroad, unduly burdensome, and not proportional to the needs of the litigation, in that it is not limited to valsartan API, recalls of products in the United States market, and the NDMA and NDEA impurities at issue in the litigation. APUSA and Aurolife also object to this request to the extent it seeks documents or information that is publicly available or available from another source that is more convenient. APUSA and Aurolife further object to this Request as it seeks documents and information that are neither relevant to any party's claims or defenses nor proportional to the needs of the deposition and the litigation by seeking production of documents and information beyond the "legal issue" as defined by the Court during the August 14, 2019 conference (*See* Tr. of August 14 Conference with Magistrate Judge Schneider (Doc. 200) at 19:19-22). APUSA and Aurolife further object to this Request on the grounds that the terms "documentation," "demonstrating," "relationship," "organization," "control," "contracts," "agreements," "ownership" and "agency" are vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, unreasonable

and neither relevant to any party's claim or defense nor proportional to the needs of the litigation, in that they purport to seek documents and information not directly related to valsartan API, recalls of products in the United States market, and the NDMA and NDEA impurities at issue in the litigation.

Notwithstanding the above, and subject to the objections asserted herein, APUSA and Aurolife will produce relevant, non-privileged documents in their possession, custody or control, if any exist, related to the alleged NDEA and NDMA impurities purportedly in valsartan API sold in the United States market.

REQUEST NO. 2: ***All contracts and agreements, including but not limited to those addressing ownership, control, parent/subsidiary relationship, and agency relationship, between and among Aurobindo Pharma USA, Inc., Aurolife Pharma LLC, and Aurobindo Pharma Limited.***

RESPONSE: APUSA and Aurolife object to those parts of this request that are duplicative of the Core Discovery production previously ordered by the Court (Doc. 88). APUSA and Aurolife further object to this Request as overbroad, unduly burdensome, and not proportional to the needs of the litigation, in that it is not limited to valsartan API, recalls of products in the United States market, and the NDMA and NDEA impurities at issue in the litigation, and in that it requests the production of "all" contracts and agreements. APUSA and Aurolife also object to this request to the extent it seeks documents or information that is publicly available or available from another source that is more convenient. APUSA and Aurolife further object to this Request as it seeks documents and information that are neither relevant to any party's claims or defenses nor proportional to the needs of the deposition and the litigation by seeking production of documents and information beyond the "legal issue" as defined by the Court during the August 14, 2019 conference (*See* Tr. of August 14 Conference with Magistrate Judge Schneider (Doc. 200) at 19:19-22). APUSA and Aurolife further object to

this Request on the grounds that the terms "contracts," "agreements," "addressing," "ownership," "control," "relationship" and "agency" are vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, unreasonable and neither relevant to any party's claim or defense nor proportional to the needs of the litigation, in that they purport to seek documents and information not directly related to valsartan API, recalls of products in the United States market, and the NDMA and NDEA impurities at issue in the litigation.

Notwithstanding the above, and subject to the objections asserted herein, APUSA and Aurolife will produce relevant, non-privileged documents in their possession, custody or control, if any exist, related to the alleged NDEA and NDMA impurities purportedly in valsartan API sold in the United States market.

REQUEST NO. 3: ***All policies and procedures addressing (1) the corporate relationship, including but not limited to ownership, control, parent/subsidiary relationship, and agency relationship, and (2) communications and access to information, between and among Aurobindo Pharma USA, Inc., Aurolife Pharma LLC, and Aurobindo Pharma Limited.***

RESPONSE: APUSA and Aurolife object to this request including its subparts (1)-(2) that are duplicative of the Core Discovery production previously ordered by the Court (Doc. 88). APUSA and Aurolife further object to this Request as overbroad, unduly burdensome, and not proportional to the needs of the litigation, in that it is not limited to valsartan API, recalls of products in the United States market, and the NDMA and NDEA impurities at issue in the litigation, and in that it requests the production of "all" policies and procedures. APUSA and Aurolife also object to this request to the extent it seeks documents or information that is publicly available or available from another source that is more convenient. APUSA and Aurolife further object to this Request as it seeks documents and information that are neither relevant to any party's claims or defenses nor proportional to the needs of the deposition and the

litigation by seeking production of documents and information beyond the "legal issue" as defined by the Court during the August 14, 2019 conference (*See* Tr. of August 14 Conference with Magistrate Judge Schneider (Doc. 200) at 19:19-22). APUSA and Aurolife further object to this Request on the grounds that the terms "policies," "procedures," "addressing," "relationship," "ownership," "control," "agency," "communications," "access" and "information" are vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, unreasonable and neither relevant to any party's claim or defense nor proportional to the needs of the litigation, in that they purport to seek documents and information not directly related to valsartan API, recalls of products in the United States market, and the NDMA and NDEA impurities at issue in the litigation.

Notwithstanding the above, and subject to the objections asserted herein, APUSA and Aurolife will produce relevant, non-privileged documents in their possession, custody or control, if any exist, related to the alleged NDEA and NDMA impurities purportedly in valsartan API sold in the United States market.

REQUEST NO. 4: ***All communications between and among employees, agents, directors, or officers of Aurobindo Pharma USA, Inc., and Aurolife Pharma LLC, and Aurobindo Pharma Limited, requesting or providing information with regard to the manufacture, production process, regulatory compliance, testing, and contamination of valsartan.***

RESPONSE: APUSA and Aurolife object to those parts of this request that are duplicative of the Core Discovery production previously ordered by the Court (Doc. 88). APUSA and Aurolife further object to this Request as overbroad, unduly burdensome, and not proportional to the needs of the litigation, in that it is not limited to valsartan API, recalls of products in the United States market, and the NDMA and NDEA impurities at issue in the litigation, and in that it requests the production of "all" communications. APUSA and Aurolife

also object to this request to the extent it seeks documents or information that is publicly available or available from another source that is more convenient. APUSA and Aurolife further object to this Request as it seeks documents and information that are neither relevant to any party's claims or defenses nor proportional to the needs of the deposition and the litigation by seeking production of documents and information beyond the "legal issue" as defined by the Court during the August 14, 2019 conference (*See* Tr. of August 14 Conference with Magistrate Judge Schneider (Doc. 200) at 19:19-22). APUSA and Aurolife further object to this Request on the grounds that the terms "communications," "employees," "agents," "directors," "officers," "requesting," "providing," "information," "regard," "manufacture," "production process," "regulatory compliance," "testing," "contamination" and "valsartan" are vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, unreasonable and neither relevant to any party's claim or defense nor proportional to the needs of the litigation, in that they purport to seek documents and information not directly related to valsartan API, recalls of products in the United States market, and the NDMA and NDEA impurities at issue in the litigation.

Notwithstanding the above, and subject to the objections asserted herein, APUSA and Aurolife will produce relevant, non-privileged documents in their possession, custody or control, if any exist, related to the alleged NDEA and NDMA impurities purportedly in valsartan API sold in the United States market.

REQUEST NO. 5: ***All communications between and among employees, agents, directors, or officers of Aurobindo Pharma USA, Inc., Aurolife Pharma LLC, and Aurobindo Pharma Limited, with regard to communications with the FDA regarding the manufacturing process or contamination of valsartan.***

RESPONSE: APUSA and Aurolife object to those parts of this request that are duplicative of the Core Discovery production previously ordered by the Court (Doc. 88). APUSA and Aurolife further object to this Request as overbroad, unduly burdensome, and not

proportional to the needs of the litigation, in that it is not limited to valsartan API and the NDMA and NDEA impurities at issue in the litigation, and in that it requests the production of "all" communications. APUSA and Aurolife also object to this request to the extent it seeks documents or information that is publicly available or available from another source that is more convenient. APUSA and Aurolife further object to this Request as it seeks documents and information that are neither relevant to any party's claims or defenses nor proportional to the needs of the deposition and the litigation by seeking production of documents and information beyond the "legal issue" as defined by the Court during the August 14, 2019 conference (*See* Tr. of August 14 Conference with Magistrate Judge Schneider (Doc. 200) at 19:19-22). APUSA and Aurolife further object to this Request on the grounds that the terms "communications," "employees," "agents," "directors," "officers," "regard," "communications," "FDA," "regarding," "manufacturing," "process," "contamination" and "valsartan" are vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, unreasonable and neither relevant to any party's claim or defense nor proportional to the needs of the litigation, in that they purport to seek documents and information not directly related to valsartan API and the NDMA and NDEA impurities at issue in the litigation.

Notwithstanding the above, and subject to the objections asserted herein, APUSA and Aurolife will produce relevant, non-privileged documents in their possession, custody or control, if any exist, related to the alleged NDEA and NDMA impurities purportedly in valsartan API sold in the United States market.

REQUEST NO. 6: ***Complete documentation of communications between and among employees, agents, directors, or officers of Aurobindo Pharma USA, Inc., Aurolife Pharma LLC, and Aurobindo Pharma Limited, with regard to the conduct and results of testing of valsartan for contamination.***

RESPONSE: APUSA and Aurolife object to those parts of this request that are duplicative of the Core Discovery production previously ordered by the Court (Doc. 88). APUSA and Aurolife further object to this Request as overbroad, unduly burdensome, and not proportional to the needs of the litigation, in that it is not limited to valsartan API, recalls of products in the United States market, and the NDMA and NDEA impurities at issue in the litigation. APUSA and Aurolife also object to this request to the extent it seeks documents or information that is publicly available or available from another source that is more convenient. APUSA and Aurolife further object to this Request as it seeks documents and information that are neither relevant to any party's claims or defenses nor proportional to the needs of the deposition and the litigation by seeking production of documents and information beyond the "legal issue" as defined by the Court during the August 14, 2019 conference (*See* Tr. of August 14 Conference with Magistrate Judge Schneider (Doc. 200) at 19:19-22). APUSA and Aurolife further object to this Request on the grounds that the terms "complete," "documentation," "communications," "directors," "officers," "regard," "conduct," "results," "testing," "valsartan" and "contamination" are vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, unreasonable and neither relevant to any party's claim or defense nor proportional to the needs of the litigation, in that they purport to seek documents and information not directly related to valsartan API, recalls of products in the United States market, and the NDMA and NDEA impurities at issue in the litigation.

Notwithstanding the above, and subject to the objections asserted herein, APUSA and Aurolife will produce relevant, non-privileged documents in their possession, custody or control,

if any exist, related to the alleged NDEA and NDMA impurities purportedly in valsartan API sold in the United States market.

REQUEST NO. 7: ***Complete documentation of communications between and among employees, agents, directors, or officers of Aurobindo Pharma USA, Inc., Aurolife Pharma LLC, and Aurobindo Pharma Limited, with regard to any change or modification to the manufacturing process for valsartan.***

RESPONSE: APUSA and Aurolife object to those parts of this request that are duplicative of the Core Discovery production previously ordered by the Court (Doc. 88). APUSA and Aurolife further object to this Request as overbroad, unduly burdensome, and not proportional to the needs of the litigation, in that it is not limited to valsartan API, recalls of products in the United States market, and the NDMA and NDEA impurities at issue in the litigation, and in that it requests the production of documents and information regarding "any" change or modification. APUSA and Aurolife also object to this request to the extent it seeks documents or information that is publicly available or available from another source that is more convenient. APUSA and Aurolife further object to this Request as it seeks documents and information that are neither relevant to any party's claims or defenses nor proportional to the needs of the deposition and the litigation by seeking production of documents and information beyond the "legal issue" as defined by the Court during the August 14, 2019 conference (*See* Tr. of August 14 Conference with Magistrate Judge Schneider (Doc. 200) at 19:19-22). APUSA and Aurolife further object to this Request on the grounds that the terms "complete," "documentation," "communications," "employees," "agents," "directors," "officers," "regard," "change," "modification," "manufacturing," "process" and "valsartan" are vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, unreasonable and neither relevant to any party's claim or defense nor proportional to the needs of the litigation, in that they purport to

seek documents and information not directly related to valsartan API, recalls of products in the United States market, and the NDMA and NDEA impurities at issue in the litigation.

Notwithstanding the above, and subject to the objections asserted herein, APUSA and Aurolife will produce relevant, non-privileged documents in their possession, custody or control, if any exist, related to the alleged NDEA and NDMA impurities purportedly in valsartan API sold in the United States market.

REQUEST NO. 8: ***All documents in the possession, custody, or control of Aruobindo Pharma USA, Inc. and/or Aurolife Pharma LLC, with regard to:***

- ***a) Contamination of valsartan,***
- ***b) Communications with the FDA with regard to potential or actual contamination of valsartan,***
- ***c) The valsartan manufacturing process, including any changes or modifications t hereto (including but not limited to the use of solvents),***
- ***d) The conduct and results of testing of valsartan for impurities or contamination,***
- ***e) The health risks posed by the valsartan contamination,***
- ***f) The ANDAs and other regulatory filings and communications with regard to valsartan, and***
- ***g) Sales and pricing of valsartan sold in the United States.***

RESPONSE: APUSA and Aurolife object to this request including its subparts (a)-(g) that are duplicative of the Core Discovery production previously ordered by the Court (Doc. 88). APUSA and Aurolife further object to this Request as overbroad, unduly burdensome, and not proportional to the needs of the litigation, in that it is not limited to valsartan API, recalls of products in the United States market, and the NDMA and NDEA impurities at issue in the litigation, and in that it requests the production of documents and information regarding "all" documents and "any" changes or modifications. APUSA and Aurolife also object to this request to the extent it seeks documents or information that is publicly available or available from another source that is more convenient. APUSA and Aurolife further object to this Request as it seeks documents and information that are neither relevant to any party's claims or defenses nor proportional to the needs of the deposition and the litigation by seeking production of documents

and information beyond the "legal issue" as defined by the Court during the August 14, 2019 conference (*See* Tr. of August 14 Conference with Magistrate Judge Schneider (Doc. 200) at 19:19-22). APUSA and Aurolife further object to this Request on the grounds that the terms "documents," "possession," "custody," "control," "regard," "contamination," "valsartan," "communications," "FDA," "regard," "potential, "actual," "manufacturing," "process," "change," "modifications," "use," "solvents," "conduct," "results," "testing," "impurities," "health risks," "posed," "ANDAs," " other regulatory filings," "sales," "pricing" and "sold" are vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, unreasonable and neither relevant to any party's claim or defense nor proportional to the needs of the litigation, in that they purport to seek documents and information not directly related to valsartan API, recalls of products in the United States market, and the NDMA and NDEA impurities at issue in the litigation.

Notwithstanding the above, and subject to the objections asserted herein, APUSA and Aurolife will produce relevant, non-privileged documents in their possession, custody or control, if any exist, related to the alleged NDEA and NDMA impurities purportedly in valsartan API sold in the United States market.

REQUEST NO. 9: ***All documents that Aurobindo Pharma USA, Inc. and/or Aurolife Pharma LLC have access to, with regard to:***

- ***a) Contamination of valsartan,***
- ***b) Communications with the FDA with regard to potential or actual contamination of valsartan,***
- ***c) The valsartan manufacturing process, including any changes or modifications t hereto (including but not limited to the use of solvents),***
- ***d) The conduct and results of testing of valsartan for impurities or contamination,***
- ***e) The health risks posed by the valsartan contamination,***
- ***f) The ANDAs and other regulatory filings and communications with regard to valsartan, and***
- ***g) Sales and pricing of valsartan sold in the United States.***

RESPONSE: APUSA and Aurolife object to this request including its subparts (a)-(g) that are duplicative of the Core Discovery production previously ordered by the Court (Doc. 88). APUSA and Aurolife further object to this Request as overbroad, unduly burdensome, and not proportional to the needs of the litigation, in that it is not limited to valsartan API, recalls of products in the United States market, and the NDMA and NDEA impurities at issue in the litigation, and in that it requests the production of documents and information regarding "all" documents and "any" changes or modifications. APUSA and Aurolife also object to this request to the extent it seeks documents or information that is publicly available or available from another source that is more convenient. APUSA and Aurolife further object to this Request as it seeks documents and information that are neither relevant to any party's claims or defenses nor proportional to the needs of the deposition and the litigation by seeking production of documents and information beyond the "legal issue" as defined by the Court during the August 14, 2019 conference (*See* Tr. of August 14 Conference with Magistrate Judge Schneider (Doc. 200) at 19:19-22). APUSA and Aurolife further object to this Request on the grounds that the terms "documents," "access," "regard," "contamination," "valsartan," "FDA," "potential," "actual," "manufacturing," "process," "changes," "modifications," "use," "solvents," "conduct," "results," "testing," "impurities," "health risks," "posed," "ANDAs," "other regulatory filings," "sales," "pricing" and "sold" are vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, unreasonable and neither relevant to any party's claim or defense nor proportional to the needs of the litigation, in that they purport to seek documents and information not directly related to valsartan API, recalls of products in the United States market, and the NDMA and NDEA impurities at issue in the litigation.

Notwithstanding the above, and subject to the objections asserted herein, APUSA and Aurolife will produce relevant, non-privileged documents in their possession, custody or control, if any exist, related to the alleged NDEA and NDMA impurities purportedly in valsartan API sold in the United States market.

REQUEST NO. 10: ***Complete documentation of any request(s) by Aurobindo Pharma USA, Inc. and/or Aurolife Pharma LLC for documents or information to be provided by Aurobindo Pharma Limited with regard to valsartan, to which Aurobindo Pharma Limited has refused or denied access.***

RESPONSE: APUSA and Aurolife object to this Request as overbroad, unduly burdensome, and not proportional to the needs of the litigation, in that it is not limited to valsartan API, recalls of products in the United States market, and the NDMA and NDEA impurities at issue in the litigation, and in that it requests the production of documents and information regarding "any" requests. APUSA and Aurolife also object to this request to the extent it seeks documents or information that is publicly available or available from another source that is more convenient. APUSA and Aurolife further object to this Request as it seeks documents and information that are neither relevant to any party's claims or defenses nor proportional to the needs of the deposition and the litigation by seeking production of documents and information beyond the "legal issue" as defined by the Court during the August 14, 2019 conference (*See* Tr. of August 14 Conference with Magistrate Judge Schneider (Doc. 200) at 19:19-22). APUSA and Aurolife further object to this Request on the grounds that the terms "complete," "documentation," "request(s)," "documents," "information," "provided," "regard," "valsartan," "refused," "denied" and "access" are vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, unreasonable and neither relevant to any party's claim or defense nor proportional to the needs of the litigation, in that they purport to seek documents and

information not directly related to valsartan API, recalls of products in the United States market, and the NDMA and NDEA impurities at issue in the litigation.

Notwithstanding the above, and subject to the objections asserted herein, APUSA and Aurolife will produce relevant, non-privileged documents in their possession, custody or control, if any exist, related to the alleged NDEA and NDMA impurities purportedly in valsartan API sold in the United States market.

REQUEST NO. 11: ***Document/data retention and destruction policies for Aurobindo Pharma USA, Inc., Aurolife Pharma LLC, and Aurobindo Pharma Limited.***

RESPONSE: APUSA and Aurolife object to this Request as overbroad, unduly burdensome, and not proportional to the needs of the litigation, in that it is not limited to valsartan API, recalls of products in the United States market, and the NDMA and NDEA impurities at issue in the litigation, and in that it requests the production of documents and information regarding "any" requests. APUSA and Aurolife also object to this request to the extent it seeks documents or information that is publicly available or available from another source that is more convenient. APUSA and Aurolife further object to this Request as it seeks documents and information that are neither relevant to any party's claims or defenses nor proportional to the needs of the deposition and the litigation by seeking production of documents and information beyond the "legal issue" as defined by the Court during the August 14, 2019 conference (*See* Tr. of August 14 Conference with Magistrate Judge Schneider (Doc. 200) at 19:19-22). APUSA and Aurolife further object to this Request on the grounds that the terms "document," "data" and "policies" are vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, unreasonable and neither relevant to any party's claim or defense nor proportional to the needs of the litigation, in that they purport to seek documents and information

not directly related to valsartan API, recalls of products in the United States market, and the NDMA and NDEA impurities at issue in the litigation.

Notwithstanding the above, and subject to the objections asserted herein, APUSA and Aurolife will produce relevant, non-privileged documents in their possession, custody or control, if any exist, related to the alleged NDEA and NDMA impurities purportedly in valsartan API sold in the United States market.

REQUEST NO. 12: ***All Aurobindo Pharma USA, Inc. or Aurolife Pharma LLC corporate meeting agendas, minutes, and exhibits thereto reflecting participation of or reference to any employee, agent, officer, or director of Aurobindo Pharma Limited with regard to valsartan.***

RESPONSE: APUSA and Aurolife object to this Request as overbroad, unduly burdensome, and not proportional to the needs of the litigation, in that it is not limited to valsartan API, recalls of products in the United States market, and the NDMA and NDEA impurities at issue in the litigation, and in that it requests the production of documents and information regarding "all" corporate meeting agendas, minutes and exhibits thereto, and "any" employee, agent, officer, or director. APUSA and Aurolife also object to this request to the extent it seeks documents or information that is publicly available or available from another source that is more convenient. APUSA and Aurolife further object to this Request as it seeks documents and information that are neither relevant to any party's claims or defenses nor proportional to the needs of the deposition and the litigation by seeking production of documents and information beyond the "legal issue" as defined by the Court during the August 14, 2019 conference (*See* Tr. of August 14 Conference with Magistrate Judge Schneider (Doc. 200) at 19:19-22). APUSA and Aurolife further object to this Request on the grounds that the terms "corporate meeting agendas," "minutes," "exhibits," "reflecting," "participation," "reference," employee," "agent," "officer," "director," "regard" "valsartan" are vague, ambiguous, overbroad

and unduly burdensome, lacking in particularity, unreasonable and neither relevant to any party's claim or defense nor proportional to the needs of the litigation, in that they purport to seek documents and information not directly related to valsartan API, recalls of products in the United States market, and the NDMA and NDEA impurities at issue in the litigation.

Notwithstanding the above, and subject to the objections asserted herein, APUSA and Aurolife will produce relevant, non-privileged documents in their possession, custody or control, if any exist, related to the alleged NDEA and NDMA impurities purportedly in valsartan API sold in the United States market.

REQUEST NO. 13: ***Documentation sufficient to identify all persons who are or were employees, agents, officers, or directors of both Aurobindo Pharma USA, Inc. or Aurolife Pharma LLC as well as employees, agents, officers, or directors of Aurobindo Pharma Limited.***

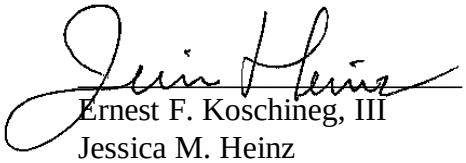
RESPONSE: APUSA and Aurolife object to those parts of this request that are duplicative of the Core Discovery production previously ordered by the Court (Doc. 88). APUSA and Aurolife further object to this Request as overbroad, unduly burdensome, and not proportional to the needs of the litigation, in that it is not limited to valsartan API, recalls of products in the United States market, and the NDMA and NDEA impurities at issue in the litigation, and in that it requests the production of documents and information regarding "all" persons. APUSA and Aurolife also object to this request to the extent it seeks documents or information that is publicly available or available from another source that is more convenient. APUSA and Aurolife further object to this Request as it seeks documents and information that are neither relevant to any party's claims or defenses nor proportional to the needs of the deposition and the litigation by seeking production of documents and information beyond the "legal issue" as defined by the Court during the August 14, 2019 conference (*See* Tr. of August 14 Conference with Magistrate Judge Schneider (Doc. 200) at 19:19-22). APUSA and Aurolife

further object to this Request on the grounds that the terms "documentation," "sufficient," "identify," "employees," "agents," "officers" and "directors" are vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, unreasonable and neither relevant to any party's claim or defense nor proportional to the needs of the litigation, in that they purport to seek documents and information not directly related to valsartan API, recalls of products in the United States market, and the NDMA and NDEA impurities at issue in the litigation.

Notwithstanding the above, and subject to the objections asserted herein, APUSA and Aurolife will produce relevant, non-privileged documents in their possession, custody or control, if any exist, related to the alleged NDEA and NDMA impurities purportedly in valsartan API sold in the United States market.

Dated: October 4, 2019

CIPRIANI & WERNER, P.C.

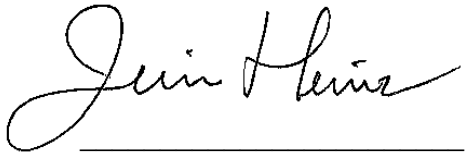


Ernest F. Koschineg, III
Jessica M. Heinz
450 Sentry Parkway East
Suite 200
Blue Bell, PA 19422
Tel: 610-567-0700
Fax: 610-567-0712
ekoschineg@c-wlaw.com
jheinz@c-wlaw.com

Attorneys for Defendants
Aurobindo Pharma USA, Inc.
and Aurolife Pharma LLC

CERTIFICATE OF SERVICE

A true and correct copy of the foregoing was served this 4th day of October 2019 on all counsel of record *via* the CM/ECF system of the United States District Court for the District of New Jersey.



Jessica M. Heinz